

# Pharmacy & Therapeutics Committee Meeting

*Formulary and Program Updates Effective 1/1/2024*

October 11, 2023  
6:30PM – 8PM



*Dale R. Folwell, CPA*  
STATE TREASURER OF NORTH CAROLINA  
DALE R. FOLWELL, CPA

# Roll Call

## **P&T COMMITTEE MEMBERS**

- David Konanc, MD
- Jennifer Burch, PharmD, CDE
- John B. Anderson, MD, MPH
- Peter Robie, MD
- Phil Seats, RPh
- Sheel Desai Solomon, MD
- Sundhar Ramalingam, MD
- Ghassan Al-Sabbagh, MD
- Laura Rachal, MD
- W. Russell Laundon, PharmD, MS, BCPS

## **PLAN STAFF & VENDORS**

### State Health Plan

- Jenny Vogel, PharmD
- Sonya Dunn, MPA, BSPH, RN
- Caroline Smart
- Sam Watts

### CVS Caremark

- Renée Jarnigan, RPh

# Ethics Awareness & Conflict of Interest Reminder

In accordance with the [Recusal Guidelines for Public Servants](#), it is the duty of every member of the Pharmacy & Therapeutics Committee, whether serving in a vote casting or advisory capacity, to avoid both conflicts of interest and appearances of conflict.

Does any Committee member have any known conflict of interest or the appearance of any conflict with respect to any manufacturers of any medication to be discussed at today's meeting?

Or, if during the course of the evaluation process if you identify a conflict of interest or the appearance of a conflict.

If so, please identify the conflict or appearance of conflict and refrain from any undue participation in the particular matter involved

# Minutes from Previous Committee Meeting

Instead of reading the minutes, copies were distributed prior to the meeting for your review.

- Are there any additions or corrections to the minutes?
- If not, the minutes will stand approved as is.

# Formulary Updates – Effective 1/1/2024

## CVS Caremark's Quarterly Formulary Update:

- Formulary Additions (including new molecular entities, line extensions, and add-backs)
- Utilization Management
- Product Exclusions
- Tier Changes (Uptier/Downtier)

## Presented by:

- Renée Jarnigan, RPh, Clinical Advisor, CVS Health
- Jenny Vogel, PharmD, State Health Plan

# Formulary Updates – New Molecular Entities

## Formulary Additions

- These are new formulary medications for the State Health Plan that are eligible for formulary inclusion as the CVS new drug to market block strategy has been satisfied.

Drug	Indication	Criteria for Approval	Tier
XACDURO (sulbactam/ durlobactam)	Treatment of adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex.	n/a	3
XENPOZYME (olipudase alfa)	Treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.	SGM	6
SOGROYA (somapacitan)	Indicated for replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (GHD) and treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH).	SGM; Specialty QL	5

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Drug	Indication	Criteria for Approval	Tier
LITFULO (ritlecitinib)	Treatment of severe alopecia areata in adults and adolescents 12 years and older.	SGM; Specialty QL	6
VEOPOZ (pozelimab)	Treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.	n/a	6

# Formulary Updates- Additions

## Formulary Additions

- All Drugs, including line extensions, new formulations of existing formulary products and add backs (products not new to market that were previously blocked by the Plan and are now added to the formulary).

Drug	Tier
budesonide-formoterol aer inh	1
MOUNJARO	2
AIRSUPRA	2
BEYFORTUS	3
LYVISPAH	2
ADALIMUMAB-ADAZ	5
AVSOLA	5

Drug	Tier
BYOOVIZ	5
CIMERLI	5
HERZUMA	5
HYRIMOZ	5
LUMRYZE	5
OGIVRI	5
TADLIQ	5



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Drug	Tier
fluticasone/salmeterol aer pwd; wixela inhub	1
fluticasone/salmeterol hfa inh	1
MULTAQ	2
LANTUS	2
DULERA	3
HUMATROPE	5
FOLLISTIM AQ	5

# Formulary Updates – Additions Questions?

# Utilization Management – GLP-1 Diabetes

**Objective:** Maintain access to diabetes GLP/GIP-GLP-1 treatments for members using appropriately while safeguarding against inappropriate/off-label use by confirming diabetes indication.

## Solutions:

- Antidiabetic GLP/GIP-GLP-1 Smart Logic PA
  - ✓ P&T Committee approved in May 2023
  - ✓ Implemented 8/1/2023

## Proposed Update:

- Edit the Smart Logic to no longer allow past use of GLP-1 agent alone to satisfy the requirement and bypass PA that validates the diabetes indication for use.
- This will help mitigate a loophole whereby past use of off label GLP-1 products lead to approval for off-label use of newly added Mounjaro

# Non-Specialty Product, Trend, and UM

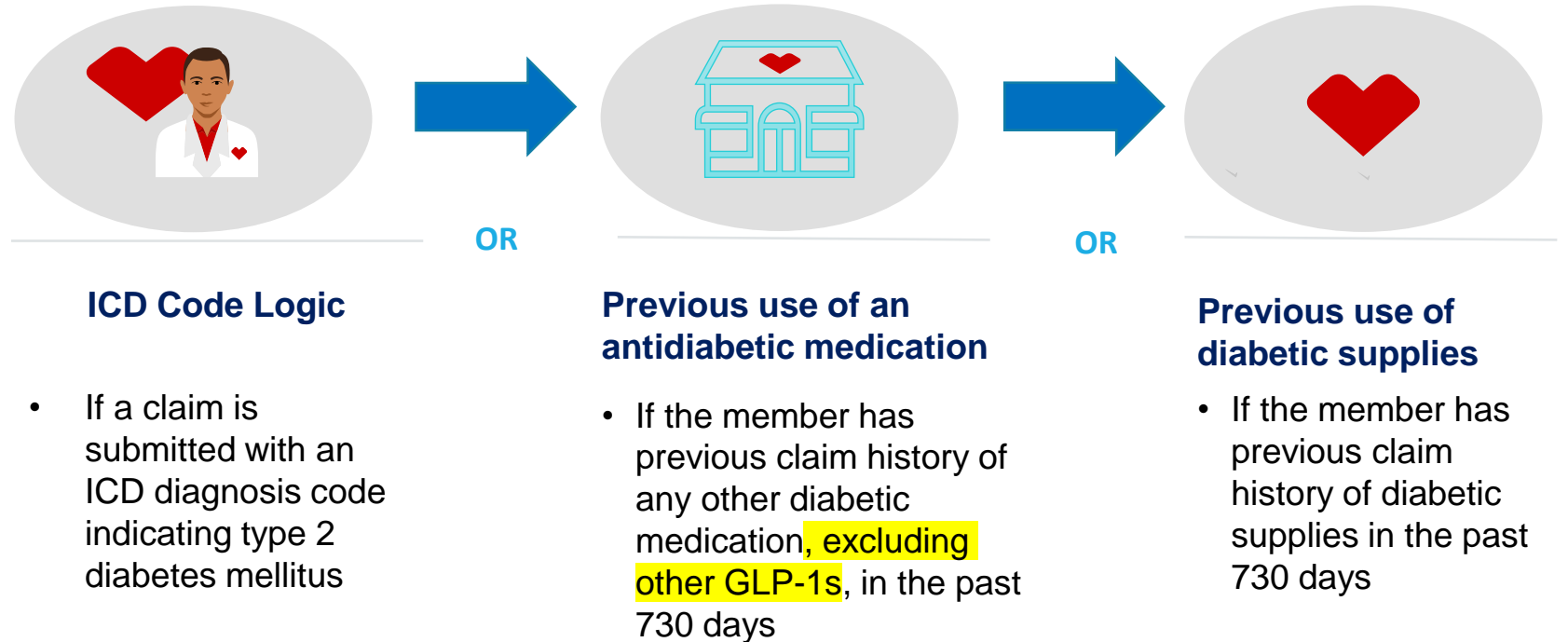
Antidiabetic GLP-1, GIP-GLP-1

## Smart Logic Utilization Management

### Smart Logic:

- Screens out patients utilizing GLP-1, GIP-GLP-1 medications for diabetes
- Patients meeting any smart logic edits will not be subject to PA to confirm diagnosis of type 2 diabetes
- Two-year lookback enables optimal review of previous claims history of diabetes

### The member will bypass PA requirements:



PA: Prior Authorization  
GLP: Glucagon-Like Peptide  
GIP: Glucose-dependent Insulinotropic Polypeptide

Layered Logic allows for optimal screen out of patients utilizing for diabetes

# Utilization Management Policy Review

## Antidiabetic GLP-1, GIP-GLP-1 Agonist PA with Logic

### Affected Medications:

- Adlyxin, Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza, Mounjaro

### Coverage Criteria:

- a diagnosis of type 2 diabetes mellitus **AND**
- a history of an A1C greater than or equal to 6.5 percent\*

### OR

- has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT)\*

### OR

- has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL\*

### OR

- has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL\*; **AND**
- fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL\*

\* Chart notes or other documentation supporting this diagnostic are submitted to CVS Health

# Formulary Updates – Utilization Management Questions?

# Formulary Updates – Product Exclusions

## Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.
- **Formulary Exclusion Exception Process:**
  - This process is available to support Plan members who, per their provider, have a medical necessity to remain on an excluded drug.
  - There may be circumstances in which the formulary alternatives may not be appropriate for some members. In this case, a member may be approved for the excluded drug with an exception process.
  - An exception is defined as a situation where the member has tried and failed (that is, had an inadequate treatment response or intolerance) to the required number of formulary alternatives; or the member has a documented clinical reason such as an adverse drug reaction or drug contraindication that prevents them from trying the formulary alternatives.
  - If a member's exception is approved that drug will be placed into Tier 3 or Tier 6 and the member will be subject to the applicable cost share.

# Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Analgesics/ Opioid Analgesics	XTAMPZA ER	251	fentanyl transdermal, hydrocodone ext-rel, hydromorphone ext-rel, methadone, morphine ext-rel
Anti-infectives/ Antiretroviral Agents/ Non-nucleoside Reverse Transcriptase Inhibitors	EDURANT	11	efavirenz
Anti-infectives/ Antiretroviral Agents/ Non-nucleoside Reverse Transcriptase Inhibitors	INTELENCE	3	etravirine
Anti-infectives/ Antiretroviral Agents/ Protease Inhibitors	KALETRA	0	atazanavir, darunavir, lopinavir-ritonavir
Anti-infectives/ Antiretroviral Agents/ Protease Inhibitors	NORVIR	4	ritonavir
Anti-infectives/ Antiretroviral Agents/ Protease Inhibitors	PREZISTA	13	atazanavir, darunavir
Anti-infectives/ Antiretroviral Agents/ Protease Inhibitors	REYATAZ	0	atazanavir, darunavir



# Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Antineoplastic Agents/ Kinase Inhibitors	IRESSA	0	erlotinib, gefitinib
Antineoplastic Agents/ Kinase Inhibitors/ Polycythemia Vera	JAKAFI	24	BESREMI
Antineoplastic Agents/ Biosimilars	KANJINTI	2	HERZUMA, OGIVRI
Antineoplastic Agents/ Kinase Inhibitors	LORBRENA	4	ALECENSA, ALUNBRIG
Antineoplastic Agents/ Kinase Inhibitors	NEXAVAR	0	sorafenib, sunitinib, CABOMETYX, INLYTA, LENVIMA
Antineoplastic Agents/ Biosimilars	TRAZIMERA	1	HERZUMA, OGIVRI

# Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Central Nervous System/ Antidepressants/ Miscellaneous Agents	WELLBUTRIN XL	95	bupropion, bupropion ext-rel (except bupropion ext-rel tablet 450 mg)
Central Nervous System/ Botulinum Toxins	MYOBLOC	1	DYSPORE, XEOMIN
Central Nervous System/ Migraine/ Monoclonal Antibodies	AIMOVIG	402	AJOVY, EMGALITY, QULIPTA
Central Nervous System/ Multiple Sclerosis Agents	COPAXONE INJ 20MG/ML	0	dimethyl fumarate delayed-rel, fingolimod, glatiramer, teriflunomide, AVONEX, BETASERON, COPAXONE 40 MG/ML, KESIMPTA, MAYZENT, OCREVUS, REBIF, TYSABRI, VUMERITY, ZEPOSIA
Central Nervous System/ Narcolepsy	XYREM	21	LUMRYZ, WAKIX, XYWAV

# Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Endocrine And Metabolic/ Antidiabetics/ Insulins	BASAGLAR	2096	LANTUS
Endocrine And Metabolic/ Antidiabetics/ Insulins	LEVEMIR	1433	LANTUS
Endocrine And Metabolic/ Central Precocious Puberty	TRIPTODUR	4	FENSOLVI, LUPRON DEPOT-PED, SUPPRELIN
Endocrine and Metabolic/ Fertility Regulators/ GNRH/ LHRH Antagonists	CETROTIDE	10	GANIRELIX ACETATE
Endocrine and Metabolic/ Human Growth Hormones	GENOTROPIN	26	HUMATROPE, NORDITROPIN
Endocrine and Metabolic/ Ovulation Stimulants, Gonadotropins	GONAL-F	9	FOLLISTIM AQ

# Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Gastrointestinal/ Opioid-Induced Constipation	RELISTOR	4	lubiprostone, SYMPROIC
Immunologic Agents/ Autoimmune Agents (Self-Administered)	AMJEVITA	3	Consult provider
Immunologic Agents/ Immunomodulators/ Immune Globulins	HYQVIA	0	CUTAQUIG
Respiratory/ Anaphylaxis Treatment Agents	EPIPEN, EPIPEN Jr, epinephrine inj (Mylan, Teva generics)	2686	epinephrine (except Mylan and Teva NDCs), AUVI-Q
Respiratory/ Steroid/ Beta Agonist Combinations	ADVAIR DISKUS	2535	fluticasone-salmeterol (except certain NDCs), Wixela Inhub, BREO ELLIPTA (except certain NDCs)
Respiratory/ Steroid/ Beta Agonist Combinations	ADVAIR HFA	607	fluticasone-salmeterol (except certain NDCs), Wixela Inhub, BREO ELLIPTA (except certain NDCs)
Respiratory/ Steroid/ Beta Agonist Combinations	SYMBICORT	2834	Budesonide-formoterol inh; fluticasone-salmeterol (except certain NDCs), Wixela Inhub, BREO ELLIPTA (except certain NDCs)

# Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Topical/ Dermatology/ Acne/ Topical	RETIN-A MICRO	7	adapalene (except adapalene pad), benzoyl peroxide, clindamycin gel (except NDC* 68682046275), clindamycin solution, clindamycin-benzoyl peroxide, dapson, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, AKLIEF, EPIDUO, ONEXTON, TWYNEO, WINLEVI
Topical/ Dermatology/ Topical	ARAZLO	134	adapalene (except adapalene pad), benzoyl peroxide, clindamycin gel (except NDC* 68682046275), clindamycin solution, clindamycin-benzoyl peroxide, dapson, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, AKLIEF, EPIDUO, ONEXTON, TWYNEO, WINLEVI
Topical/ Ophthalmic/ Retinal Disorders	LUCENTIS	1	BYOOVIZ, CIMERLI
Topical/ Ophthalmic/ Retinal Disorders	EYLEA	11	BYOOVIZ, CIMERLI

# Formulary Updates – Hyperinflation Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Topical/ Dermatology/ Acne/Oral	isotretinoin 25mg cap; isotretinoin 35mg cap	2	Isotretinoin capsule 20mg, 30mg, 40mg

# Formulary Updates – Exclusions Questions?

# Brand-Over-Generic Strategy

- Claims for the brand adjudicate at the generic cost share for members, which is typically the tier that includes low-cost generic alternatives.
- The strategy maintains the generic member copay/coinsurance for the brand product.
- Supports the lowest net cost formulary principle and extends savings to members.

Drug	Change Type	Tier	# Utilizers (6 mo.)
GANIRELIX	Downtier	6 → 4	
ganirelix; fyremadel	Exclude	4 → NC	

# Formulary Updates – Downtiers

## Movement to Preferred Status

- Typically, branded medications that are added as preferred products to provide additional treatment options.
- All the following products will be moving from a higher tier to a lower tier.

Drug	Tier Change
DYSPORT	3 → 2
XEOMIN	3 → 2
OPZELURA	3 → 2
KRAZATI	6 → 5
LUMAKRAS	6 → 5
PHEBURANE	6 → 5
BESREMI	6 → 5



# Formulary Updates – Uptiers

## Movement to Non-preferred Status

- Typically, branded medications that have readily available generic alternatives, biosimilars or other preferred formulary alternatives in the therapeutic class.
- All the following products will be moving from a lower tier to a higher tier.

Drug	# Utilizers (6 mo)	Alternatives	Tier Change
ANAPROX DS	0	diclofenac sodium delayed-rel, ibuprofen, naproxen, diflunisal, etodolac, meloxicam, nabumetone, oxaprozin, sulindac	2 → 3
NORPACE CR	1	disopyramide	2 → 3
LANCETS (other than ACCU-CHEK or ONETOUCH)	269	ACCU-CHECK, ONETOUCH	2 → 3
ANASPAZ	0	dicyclomine, hyoscyamine sulfate, hyoscyamine sulfate orally disintegrating tabs	2 → 3
TEXACORT SOL 2.5%	1	alclometasone cream and ointment 0.05%, desonide cream, lotion, and ointment 0.05%, fluocinolone acetonide solution 0.01%, hydrocortisone cream 2.5%, hydrocortisone cream and ointment 0.5% and 1%, hydrocortisone lotion 1%	2 → 3
DERMA-SMOOTH OIL	8	calcipotriene ointment 0.005%, calcipotriene solution 0.005%, ENSTILAR	2 → 3

# Formulary Updates – Uptiers

## Movement to Non-preferred Status

- Typically, branded medications that have readily available generic alternatives, biosimilars or other preferred formulary alternatives in the therapeutic class.
- All the following products will be moving from a lower tier to a higher tier.

Drug	# Utilizers (6 mo)	Alternatives	Tier Change
RHOFADE	69	azelaic acid gel, brimonidine gel, metronidazole, FINACEA FOAM, SOOLANTRA	2 → 3
EVOTAZ	3	atazanavir or darunavir plus ritonavir; SYMTUZA	2 → 3
PREZCOBIX	34	atazanavir or darunavir plus ritonavir; SYMTUZA	2 → 3
ILARIS	6	Consult provider	5 → 6

# Formulary Updates – Uptiers Questions?

# Summary of Formulary Changes Effective 1/1/24

## NEW MOLECULAR ENTITIES

- 5 new drug products were added to the formulary

## OTHER FORMULARY ADDITIONS

- 20 additional products were added to the formulary

## UTILIZATION MANAGEMENT

- SGM/Specialty QL for LITFULO
- SGM for XENPOZYME
- UM FOR GLP-1 Diabetes Medications

## PRODUCT EXCLUSIONS

- 36 products were excluded impacting 13,234 members

## UPTIERS/DOWNTIERS

- 17 product had tier movements

# New Business?

# Upcoming Meeting Dates for 2024

- Wednesday, February 21, 2024
- Wednesday, May 8, 2024
- Wednesday, August 14, 2024
- Wednesday, October 9, 2024